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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,387

08/01/2003

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08/08/2007

EXAMINER

LAMPRECHT, JOEL

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

08/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/632,387

Applicant(s)

BARNES ET AL.

Examiner

Joel M. Lamprecht

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/3/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The action originally mailed from 1/24/07 did not include rejections of preliminarily amended claims 20-26. The following action is believed to address all pending claims including independent claims 1, 8, 15, 20, 22, and 25. The statutory period for reply has been reset to the date of this action accordingly.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 7, 8, 9, 10, 14-16, 19, 20-22, 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (US 5,452,723). Wu et al disclose a method for diagnosing disease comprising generating data for Raman, fluorescence and diffuse reflectance spectra and images by direct optical measurement of tissue (in vivo or ex vivo) (Abstract, Col 1 Lines 25-45, Col 3 Lines 22-30, Claim 16), storing data as a library (Fig 15a/b and Fig 16a/b, Col 21 Lines 58- Col 22 Line 20), performing classification decisions to identify diseased or cancerous/precancerous tissues (Col 5 Line 15-30, (Col 3 Line 13-32, Col 23 Line 1-25), displaying images or data results to identify the state of tissues (Fig 13-16a/b), fusing data, and depth profiling as a function of time gating for profiling tissues (Col 6 Line 44-Col 7 Line 15 and Col 7 Line 28-35 for simulations to probe for depth profiling through Monte Carlo simulation). Col 6 Line 5 through Col 8 Line 55 disclose further measuring the area or volume in an unknown

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patient or using a known volume of tissue to calculate concentration and volume of tissue components in vivo (Col 1 Line 49-55). Wu et al. disclose an apparatus for identifying disease comprising sources of light for each of the desired spectra, multiple rotating mirror interfaces, tissue interface for illuminating tissue of a patient, image analysis modules for receiving light from a mirror interface with at least a non-imaging spectrometer with rotatable gratings, and system for taking diagnostic information according to diffuse reflectance and ultraviolet/visible light from the same initial beam alternatively (Col 4 Line 45 - Col 6 Line 35). Finally Wu et al. discloses an endoscope and fiber optic probe for the tissue interface (Figure 4, Clm 20, Col 6 Line 9-30).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 5,452,723) in view of Kaneko (US 5,749,830) and in further view of Burgess et al. (Article attached). Wu et al disclose a method for diagnosing disease comprising generating data for Raman, fluorescence and diffuse reflectance spectra and images by direct optical measurement of tissue (in vivo or ex vivo) (Abstract, Col 1 Lines 25-45, Col 3 Lines 22-30, Claim 16), storing data as a library (Fig 15a/b and Fig 16a/b, Col 21 Lines 58- Col 22 Line 20), performing classification decisions to identify diseased

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tissues (Col 5 Line 15-30, (Col 3 Line 13-32, Col 23 Line 1-25), displaying images or data results to identify the state of tissues (Fig 13-16a/b), fusing data, and depth profiling as a function of time gating for profiling tissues (Col 6 Line 44-Col 7 Line 15 and Col 7 Line 28-35 for simulations to probe for depth profiling through Monte Carlo simulation). Wu et al. do not specifically provide time gating to reduce interferences between Raman and fluorescence measurements, although time gating and phase manipulations are mentioned, and does not provide specific fusing means for combining the spectral library of patient-specific data with the patient data. Attention is then directed to the secondary reference by Kaneko (US 5,749,830) in the same area of endeavor, which describes a method of fusing images and image data to provide for diagnosis of patient tissue from stored data in computer memory (Fig 6-7, 11 and Col 62 Line 28- Col 63 Line 7). Attention is also directed to the secondary reference by Burgess et al. which describes time gating as a means to reduce interferences from surface scattering and/or to reduce or remove interferences between Raman and fluorescence measurements (Abstract and Experimental Data Section 2). It would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized the fusing and storage methods of Kaneko with the phase-gating methods taught by Burgess et al. in the method for diagnosing disease disclosed by Wu et al. to enable the best possible optical measurements and most accurate images for diagnosis.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Patent 5,762,608 by Benaron et al. discloses methods for creating algorithms to diagnose tissue image data from fluorescence and other data, and gives further mention to the creation of a multitude of images over time for comparison. The enclosed article by Welch et al. gives a discussion of how Monte Carlo simulations can enable scientists to better understand propagation of fluorescent light in a tissue or other water-based substance. Patent 5,280,788 is also cited as being an early source of optical tissue diagnosis, as well as patent 6,690,966 for the use of CCD arrays to store image data for comparison and diagnosis of tissues. The Applicant's also submitted an article by Liu et al. from J. Photochem. Photobiol. B Biol, 16 (1992) 187-209 which is particularly relevant to Applicant's preferred embodiments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML
7/7/07


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